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First of all let me say how grateful I am for having the opportunity to address this Congressional committee. I am also concerned that such a committee meeting on the "Elusive Antidotes of CBRN Countermeasures" must be held in June of 2005. Before I begin my formal presentation I would like to emphasize to the committee that besides my training in immunology and scientific success in developing immunotherapeutic approaches to treating cancer and infectious diseases, I have been a volunteer on federal, state and county committees for Homeland Security. From 1984 to 1989 I directed the commerce departments Biotechnology Advisory Committee, and recently directed the Frederick County Local Emergency Planning Committee responsible for Weapons of Mass Destruction threat assessment, preparedness and response.

I would like to tell you about the successful development of a unique therapy for Botulinum toxin exposure, which consists of scientific success and frustration. The seven serotypes of botulinum toxin have been identified as the most dangerous biological substances and the most likely biological weapon of mass destruction. The success is that my company Intracel, through a DoD contract

between 1991 and 1996 was able to successfully develop a heptavalent equine antibody product that was efficacious in combating the seven serotypes of Botulinum toxin, was safe in humans and was FDA approved for emergency use. We made 5000 therapeutic doses before the project was terminated by the JPO in 1996. It was terminated at this point because we had proof of principal and a Botulinum crises was improbable. Since 9/11 however the improbable became probable.

Today, Federal officials fear the world is vulnerable to such an attack and that we are ill prepared if one were to occur. In fact, Tommy Thompson in his exit speech declared that he was surprised that such an attack had not already occurred. Dr. Anthony Fauci of the NIH/NIAID is quoted as pointing out that this is one of the Federal governments top bioterrorism interests, and we are "marshalling all available resources". This statement was made in 2002, yet as far as I know as of last year we still only had the residual 3000 therapeutic doses left over from Intracel's previous effort.

This is my frustration. We have been successful in overcoming the scientific hurdles to produce this important therapeutic product; however, we have not been successful in fulfilling our destiny of producing the hundreds of thousands of doses necessary to protect our military and civilian populations at risk.

The NIH has used considerable resources to fund grants to make recombinant vaccines for protection of Botulinum infection and to

develop drugs which would interfere with the enzymatic activity of the organism. These efforts, however, worthwhile are problematic, 10 year endeavors. Intracel holds the intellectual property, over 300 standard operating procedures and all of the necessary equipment to produce the proven, heptavalent equine therapeutic product and was willing and capable of generating private funds to develop a subsidiary that would build a validated manufacturing facility and produce 50,000 therapeutic doses in 2 years. The yield would be 100,000 or more doses each year thereafter. Clearly, we thought we were the poster child of Bioshield. However, we could not get the government to give us a written commitment to purchase the product based on our success in meeting their expectations.

The CDC, the agency responsible for developing this product since the late 1990s, did finally approve a contract with a foreign company to make heptavalent equine Botulism antitoxin. As of last year, they had not generated any therapeutic doses. In 2002 we were contacted by a senior member of NIH/NIAID (Dr. Dennis Lang) who asked us to generate a grant proposal which would fund Intracel to produce the product. Although I questioned this approach, I did comply but the grant was turned down due to the NIH “color of money”. The embarrassed NIH officers then encouraged me to submit an unsolicited proposal to the CDC, which I did, and this too was turned down. At the same time I visited several congressmen and directors of responsible DoD and NIH research laboratories, and Congressman Shays shared this experience through a letter to the directors of HHS and DHS. No letter of commitment was

forthcoming; in fact many of them claimed that they did not have the authority to make a commitment. This was very frustrating and we finally gave up.

It seems to me that the government agencies are not really marshalling its efforts to deal with this problem. The agencies have relegated down the ranks to the contract and grants people. If they have the urgency of the matter, it has not overcome the status quo. In fact, much of the money has been devoted to basic research at the expense of the less problematic, pragmatic approach.

I would like to know what we would have done last year, or this year or next year if such a botulinum toxin weapon was used in the US. Clearly, the Bioshield concept with all of its good intentions has not gained the strength to overcome the status quo. I would like to repeat, Intracel was not asking the government to pay for the production of this important component of our medical armamentarium for Biodefense, Intracel was asking the government to give us a commitment to buy the product if it met specifications already paid for by the DoD.

Thank you for listening.